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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/715,910
Filing Date: November 18, 2003
Appellant(s): DAN ET AL.

Robert E. Hanson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12 January 2009 appealing from the Office action mailed 26 March 2008

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

As there appears to be a problem with the Office's scanning of Appellant's Exhibit A (Kulkarni et al, US Patent 6,365,407, filed March 2001), a copy is provided here as Exhibit A.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

A. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kulkarni et al (US Patent 6,365,407, filed March 2001) in view of Packer et al (1995, Free Rad. Biol. Med. 19:227-250).

The claims are drawn to a method comprising culturing a plant cell on a media comprising 5 μM to 100 μM lipoic acid.

Kulkarni et al disclose a method comprising culturing a Taxus cell on a medium comprising 1-5 mg/l of antioxidants (claim 5). Kulkarni et al do not disclose lipoic acid as the antioxidant.

Packer et al teach lipoic acid is a biological antioxidant (Table 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method comprising culturing a plant cell on a medium comprising an antioxidant as taught by Kulkarni et al to use lipoic acid as described in Packer et al as the antioxidant. Packer et al teaches that lipoic acid is the "ideal", "universal antioxidant" (pg 228, right column, paragraph 2). It would have thus been obvious for one of skill in the art to try lipoic acid as the oxidant in the method of culturing a Taxus cell taught by Kulkarni et al.

Kulkarni et al teaches use of 1-5 mg/l antioxidant. As the molecular weight of lipoic acid is 206.32, 1-5 mg/L would be a concentration of 5-25 μM.

B. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benson et al (1997, Phyton 37(3):31-38 in view of Packer et al (1995, Free Rad. Biol. Med. 19:227-250).

The claims are drawn to a method comprising culturing a plant cell on a media comprising 2 μM to 100 μM lipoic acid.

Benson et al disclose a method comprising culturing a plant cell on media (Fig. 1) and that plant cell culture is affected by free radicals (Table 1). Benson et al do not disclose use of antioxidants in plant tissue culture media.

Packer et al teach lipoic acid is a biological antioxidant (Table 1).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method comprising culturing a plant cell on media as taught by Benson et al to use lipoic acid as described in Packer et al an as antioxidant in the media. Packer et al teaches that lipoic acid is the "ideal", "universal antioxidant" (pg 228, right column, paragraph 2). One of ordinary skill in the art would have been motivated to do so because Benson et al suggests testing the effects of antioxidants on plant tissue culture (paragraph spanning pg 36-37). One of skill in the art would try lipoic acid because Packer et al teaches that lipoic acid is the "ideal", "universal antioxidant" (pg 228, right column, paragraph 2).

In the process of trying lipoic acid, one would test various concentrations of lipoic acid in the medium; these concentrations would include low ones in the range of 2 μM to 100 μM, as one would be cautious when first testing a new media component.

(10) Response to Argument

A. The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Kulkarni et al (US Patent 6,365,407, filed March 2001) in view of Packer et al (1995, Free Rad. Biol. Med. 19:227-250).

The examiner did not rely on impermissible hindsight reasoning

Appellant urges that nothing in the references provides suggestion or motivation to use an antioxidant in connection with plant transformation (Brief pg 4).

This is not persuasive because the claims are not drawn to plant transformation. The only method step is culturing a plant cell on medium containing lipoic acid; the preamble is given no patentable weight. "Plant transformation" before "media" was also given no weight, because any plant culture media can be used in some step or another of plant transformation. For example, a minimal medium without a selection agent can be used when the plant transformation selectable marker is green fluorescent protein, wherein the selection is done visibly.

Appellant urges that no teaching was shown for supporting a basis for using an antioxidant in connection with transformation media, let alone lipoic acid, and there was not even any showing that one would want to modify an existing transformation medium (Brief pg 4).

This is not persuasive because any plant culture media can be used in some step or another of plant transformation. The only method step is culturing a plant cell on medium containing lipoic acid. Kulkarni et al teach culturing a plant cell on plant culture media

containing an antioxidant; thus, there is basis for using an antioxidant in connection with the medium. Further, Packer et al, in teaching that lipoic acid is the ideal antioxidant, provides motivation for using it as the antioxidant in Kulkarni et al's method of culturing a plant cell.

Appellant urges that it would not be obvious to try to modify existing methods of transforming and regenerating a transformed plant using a transformation media containing lipoic acid because the number of variables that can be modified in such a method is nearly limitless (Brief pg 4-5).

This is not persuasive. The claims are not drawn to methods of transforming and regenerating a transformed plant. The variable in Kulkarni et al's medium is the choice of antioxidant; the other medium components are not altered (see claim 3). Thus, this is the most obvious component to modify.

Appellant urges that *KSR* indicated that there must be a design or market need and a finite number of predictable solutions, all elements not established in this rejection, including a motivation to modify an existing transformation medium; a desire to make it better would not be legitimate because anything would fall under such an approach and there was no showing that the existing transformation media were considered inadequate (Brief pg 5).

This is not persuasive. The motivation to modify the medium comes from Packer et al's teaching that lipoic acid is the ideal antioxidant. This teaching also limits the number of predictable solutions; there can be only one "ideal". Given that Kulkarni et al taught that the presence of antioxidants prevented phenolic oxidation of the callus, resulting in good callus growth (column 3, lines 52-59), one would have been motivated to find other antioxidants that did an even better job than the ones they teach.

Appellant urges that the only disclosure that the use of an antioxidant for transformation might have a benefit is from Appellant's specification; the rejection is based on hindsight reconstruction (Brief pg 5-6).

This is not persuasive because the instant claims are not drawn to transformation, as they have no transformation step. Kulkarni et al teach a method of culturing a plant cell on medium containing an antioxidant.

Appellant has not shown that the claimed invention yields unexpected results

Appellant urges that working examples demonstrate the claimed invention results in an increase in transgenic plant production (Brief pg 6).

This is not persuasive. First, the claims are not drawn to transgenic plant production, as there are no transformation or plant regeneration steps. Second, Appellant has provided no comparison to growth on medium containing other antioxidants.

Appellant urges that treatment with 10 μM lipoic acid increased the percentage of transgenic plants produced per explant, and treatment with 10 and 50 μM lipoic acid increased the percentage of explants having high transient expression, (Brief pg 6-7).

This is not persuasive. First, the claims are not drawn to transgenic plant production, as there are no transformation or plant regeneration steps; the only method step is culturing a plant cell on a medium containing lipoic acid. Second, the only comparison Appellant provided is to medium containing no antioxidant. However, the correct comparison here would be to growth on medium containing one of the antioxidants taught by Kulkarni et al. Appellant has not provided such a comparison; thus, there is no showing of unexpected results.

Appellant urges that treatment at 5, 10, 50 and 100 μM lipoic acid increased the number of explants scored as low tissue-browning (Brief pg 8).

This is not persuasive. This is not surprising, as Kulkarni et al already taught that the presence of antioxidants prevented phenolic oxidation (*i.e.*, browning) of the callus, resulting in good callus growth (column 3, lines 52-59). Appellant has not provided a comparison to growth on medium containing one of the antioxidants taught by Kulkarni et al; thus, there is no showing of unexpected results.

Appellant urges that 6-9 μM lipoic acid increased the transformation efficiency of potato and reduced the number of escapes, and various concentrations of lipoic acid increased the transformation efficiency of wheat, soybean and cotton (Brief pg 8-12).

This is not persuasive. First, the claims are not drawn to transgenic plant production, as there are no transformation or plant regeneration steps; the only method step is culturing a plant cell on a medium containing lipoic acid. Second, Appellant has not provided a comparison to growth on medium containing one of the antioxidants taught by Kulkarni et al.

Further, even if there were some unexpected results, objective evidence of nonobviousness must be commensurate in scope with the claims. Claim 3 is drawn to use of 5-1500 μM lipoic acid, claim 2 to use of 2-200 μM lipoic acid, and claim 1 to an even greater concentration range. None of Tables 1-3, 7, 9-10 or 13 test concentrations greater than 100 μM lipoic acid. Tables 12-13 show efficiencies similar to the no antioxidant control for ranges up to 100 μM lipoic acid. Thus, Appellant has not shown objective evidence of nonobviousness commensurate in scope with the claims.

Appellant urges that nothing in the art suggests any benefit or even a basis for making it obvious to try to use an antioxidant in the context of plant transformation (Brief pg 12).

This is not persuasive. The claims are not drawn to plant transformation, as there are no plant transformation steps. The only method step is culturing a plant cell on a medium containing lipoic acid, which is obvious over Kulkarni et al in view of Packer et al.

The cited references provide an expectation of success

Appellant urges that the cited art fails to teach or suggest the use of any antioxidant in connection with a transformation medium (Brief pg 12-13).

This is not persuasive. The claims are not drawn to plant transformation, as there are no plant transformation steps. The only method step is culturing a plant cell on a medium containing lipoic acid. Kulkarni et al teach a method of culturing a plant cell on a medium containing an antioxidant.

Appellant urges that Kulkarni et al used antioxidant to aid taxane production, and studies were carried out with or without antioxidants, and in Packer there is no connection of lipoic acid to plant cells or plant transformation; thus, one of skill in the art would not expect the use of lipoic acid to yield successful results in the context of the current invention (Brief pg 13).

This is not persuasive. Kulkarni et al taught that the presence of antioxidants prevented phenolic oxidation of the callus, resulting in good callus growth (column 3, lines 52-59). Appellant has not pointed to where Kulkarni et al used media without antioxidants (Table 2 indicates the concentration range is 1.0 -5.0 mg/L, which would be a concentration of 5-25 μM), but given Kulkarni et al's teaching and claims, one of skill in the art would use antioxidants in

plant cell culture. Packer et al teaches that lipoic acid is the "ideal", "universal antioxidant" (pg 228, right column, paragraph 2). That Packer et al does not discuss plant cells is not relevant in light of this teaching.

B. The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Benson et al (1997, Phyton 37(3):31-38) in view of Packer et al (1995, Free Rad. Biol. Med. 19:227-250).

The cited references provide an expectation of success

Appellant urges that Packer relates to culturing mammalian cells, not plant transformation (Brief pg 14).

This is not persuasive because Packer et al teaches that lipoic acid is the "ideal", "universal antioxidant" (pg 228, right column, paragraph 2). That Packer et al does not discuss plant cells is not relevant in light of this teaching. Further, the instant claims are not drawn to plant transformation.

Appellant urges that Benson et al states that there is no evidence to implicate free radicals etc as causal agents in genetic instability in plant cultures, and warn that oxidative processes have a positive and negative role in in vitro development (Brief pg 14-15).

This is not persuasive. The instant claims are not drawn to plant regeneration and development; they are drawn to a method of culturing a plant cell on a medium containing lipoic acid.

Appellant urges that Benson et al therefore discloses that free radicals have a beneficial impact on cell cultures; one of skill in the art would not interpret it to teach or suggest the use of

antioxidants in tissue culture in general, demonstrating the lack of reasonable expectation of success in using lipoic acid in a method of plant transformation (Brief pg 15).

This is not persuasive. Benson et al disclose that free radicals have beneficial and detrimental impacts on cell cultures, depending on cell culture age. Further, Benson et al teach that "[f]ree radical activity is associated with stress and it is a contributory factor in culture recalcitrance" (pg 33, paragraph 2).

Appellant urges that Benson actually teaches that studies must be done using both pro- and anti-oxidants, demonstrating that antioxidants might be beneficial or detrimental, and does not teach antioxidants in plant transformation media or teach lipoic acid (Brief pg 15).

This is not persuasive because using antioxidants in plant media is suggested; the suggestion to test pro-oxidants does not negate that teaching. Plant transformation media encompasses any plant culture medium, as discussed above. The teaching to use lippoic acid comes from Packer et al.

Appellant urges that Benson cautions against the use of antioxidants in plant culture medium because free radicals play a role in plant development (Brief pg 16).

This is not persuasive because the claims are merely drawn to a method of culturing a plant cell on medium containing lipoic acid; plant development and regeneration is not part of the claims.

Appellant urges that Benson et al teaches away from addition of an antioxidant to plant culture media (Brief pg 16-17).

This is not persuasive because Benson et al discloses that free radicals have beneficial and detrimental impacts on cell cultures, depending on cell culture age. Further, Benson et al

teach that "[f]ree radical activity is associated with stress and it is a contributory factor in culture recalcitrance" (pg 33, paragraph 2).

Appellant has not shown that the claimed invention yields unexpected results

Appellant urges that treatment with 10 μM lipoic acid increased the percentage of transgenic plants produced per explant, treatment with 10 and 50 μM lipoic acid increased the percentage of explants having high transient expression, that treatment at 5, 10, 50 and 100 μM lipoic acid increased the number of explants scored as low tissue-browning, 6-9 μM lipoic acid increased the transformation efficiency of potato and reduced the number of escapes, and various concentrations of lipoic acid increased the transformation efficiency of wheat, soybean and cotton (Brief pg 17-18).

The claims are not drawn to transgenic plant production, as there are no transformation or plant regeneration steps; the only method steps is culturing a plant cell on a medium containing lipoic acid. As oxidation results in callus browning, a decrease in tissue browning is not surprising or unexpected.

The only comparison Appellant provided is to medium containing no antioxidant. However, the correct comparison here would be to growth on medium containing antioxidants. Appellant has not provided such a comparison; thus, there is no showing of unexpected results.

Further, even if there were some unexpected results, objective evidence of nonobviousness must be commensurate in scope with the claims. Claim 3 is drawn to use of 5-1500 μM lipoic acid, claim 2 to use of 2-200 μM lipoic acid, and claim 1 to an even greater concentration range. None of Tables 1-3, 7, 9-10 or 13 test concentrations greater than 100 μM

lipoic acid. Tables 12-13 show efficiencies similar to the no antioxidant control for ranges up to 100 μM lipoic acid. Thus, Appellant has not shown objective evidence of nonobviousness commensurate in scope with the claims.

Appellant urges that Packer relates to lipoic acid in mammalian systems and Benson merely teaches that tissue culture is affected by free radicals, teaching away from the use of antioxidants (Brief pg 18).

This is not persuasive. The claims are merely drawn to a method of culturing a plant cell on medium containing lipoic acid; plant development and regeneration is not part of the claims.

Benson et al discloses that free radicals have beneficial and detrimental impacts on cell cultures, depending on cell culture age. Further, Benson et al teach that "[f]ree radical activity is associated with stress and it is a contributory factor in culture recalcitrance" (pg 33, paragraph 2).

The examiner did not rely on impermissible hindsight reasoning

Appellant urges that Benson et al teach the positive affects of free radicals on in vitro plant development, and Packer does not discuss plant transformation; there is nothing that would lead one of skill in the art to arrive at the claimed invention (Brief pg 18-19).

This is not persuasive. The claims are not drawn to plant transformation. The only method step is culturing a plant cell on medium containing lipoic acid. Benson et al teach that "[f]ree radical activity is associated with stress and it is a contributory factor in culture recalcitrance" (pg 33, paragraph 2). Packer et al teaches that lipoic acid is the "ideal", "universal

antioxidant" (pg 228, right column, paragraph 2). That Packer et al does not discuss plant cells is not relevant in light of this teaching.

(11) Related Proceeding(s) Appendix

For the above reasons, it is believed that the rejections should be sustained.

(12) Exhibit Appendix

Exhibit A: Kulkarni et al (US Patent 6,365,407, filed March 2001)

Respectfully submitted,

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